Investigators – Hands On Training
Spirometry

iSpire™
INSPIRING RESPIRATORY HEALTH

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Agenda

INSPIRING RESPIRATORY HEALTH

- Consistent method/coaching
- Acceptable tests vs poor tests
- Protocol specifics
- Calibration and Linearity
- Forced Vital Capacity (and FEV1)
- Reports
- eQueries
- CTMT

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Windows Login

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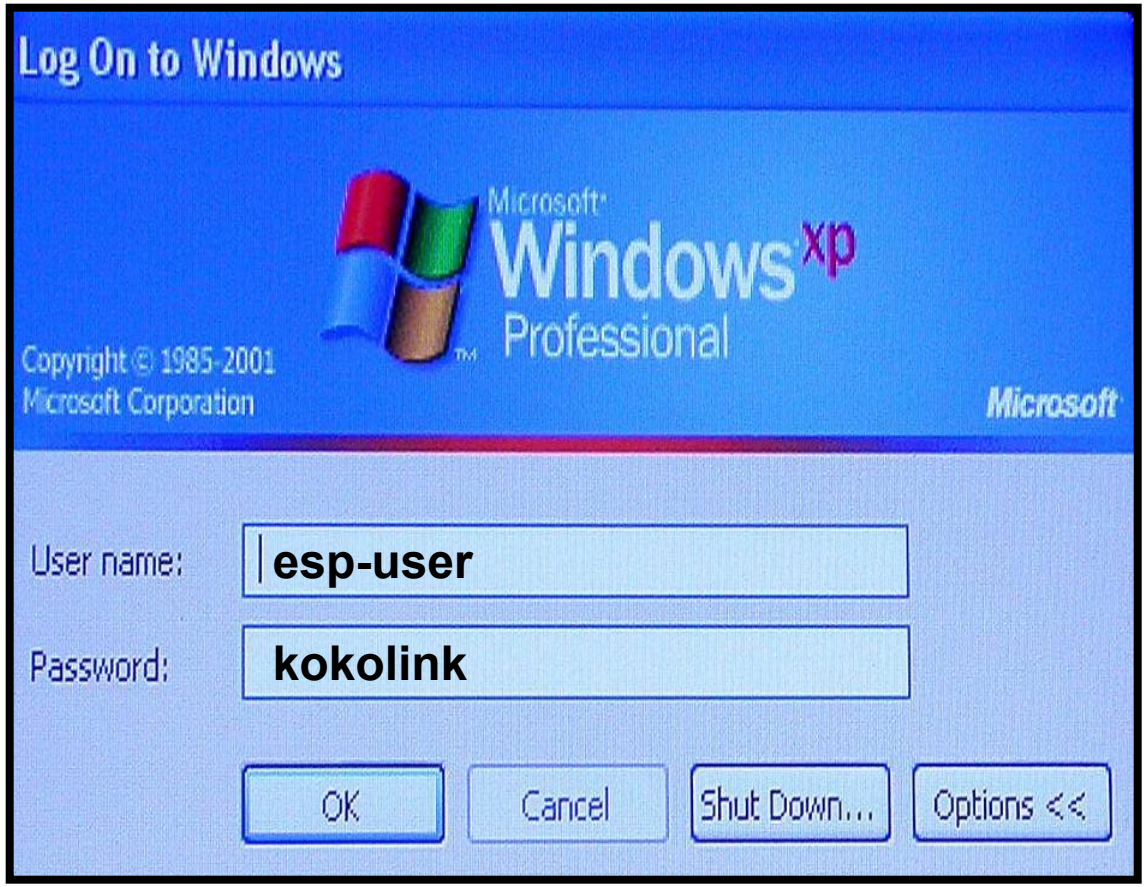

- User name: esp-user
- Password: kokolink
- Click the "**OK**" button
- The system will advance to synchronization screen
- **NOTE:** *please use this same login if the screen saver is activated*

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Synchronization Screen

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Starting eSP

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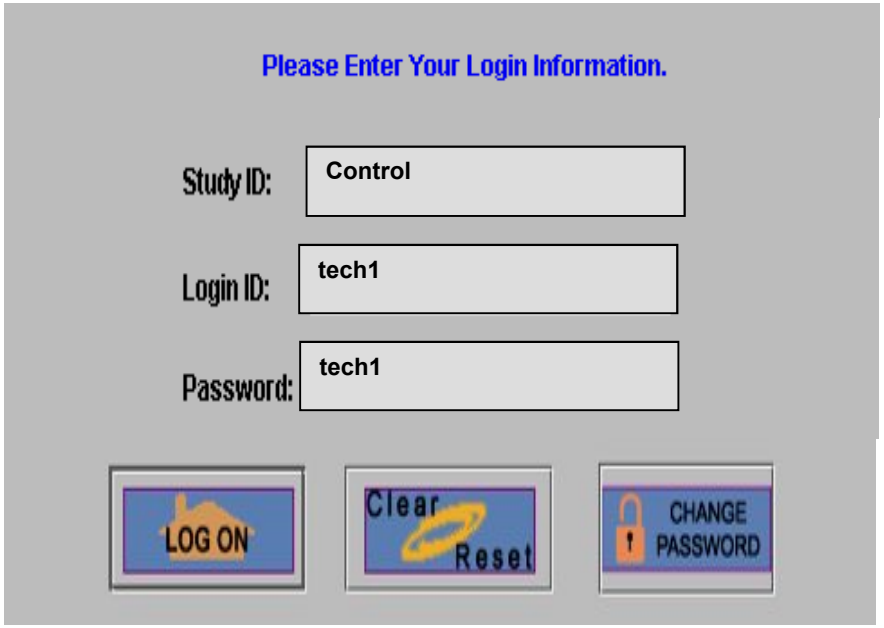

When Synchronization is complete the eSP login screen will appear.

Study ID: Control

Login: tech1

Password: tech1

Click on the "**Log On**" button

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Calibration and Linearity

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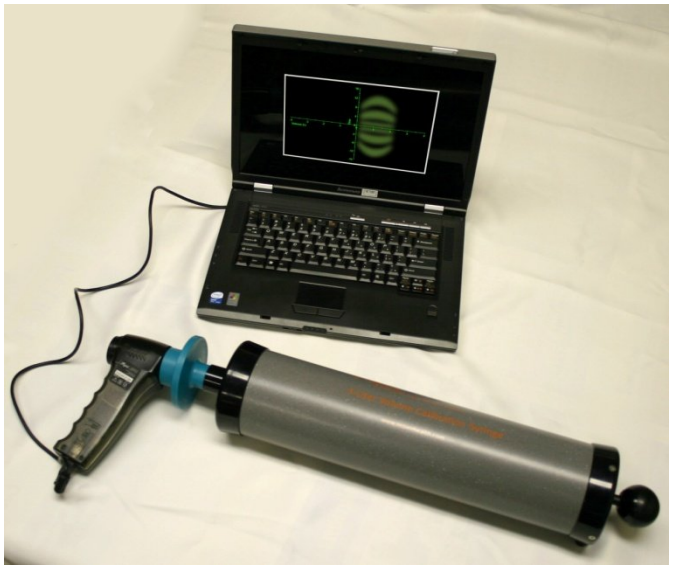
Calibration

- Ensures accuracy
- Three different flow rates are required: slow; medium; and fast
- Reports generated for each successful calibration must be printed and filed.
- Calibration must be performed on each testing day. Successful calibration is required before testing is permitted.

Linearity

- An additional volume calibration check to assess accuracy across all required flow rates
- Performed weekly, after a calibration.



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Weather Station

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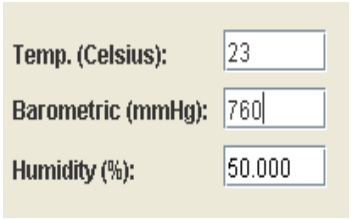
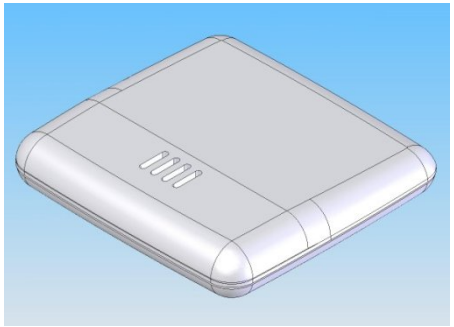
Hardware connects via USB to laptop.

Software automatically captures environmental values prior to calibration.

- ambient temperature (°C),
- barometric pressure (mmHg)
- relative humidity (%)



Be sure not to place the weather station near a heat or cooling source, such as the computer or an air-conditioning duct.



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Printing Calibration Report

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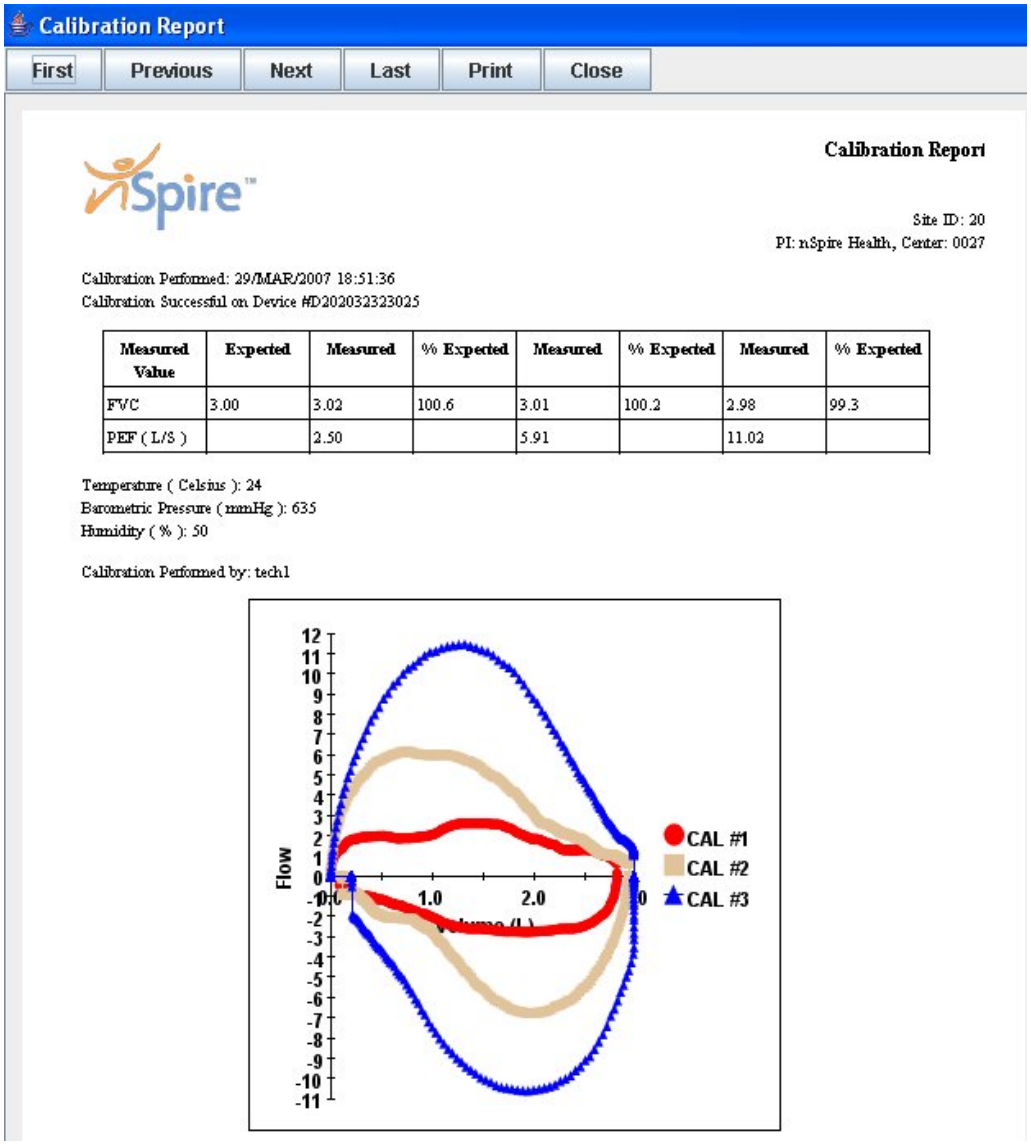

If the calibration was successful the report will appear.

This the only opportunity to print this report.

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Demonstration and Practice

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Windows and Study Login

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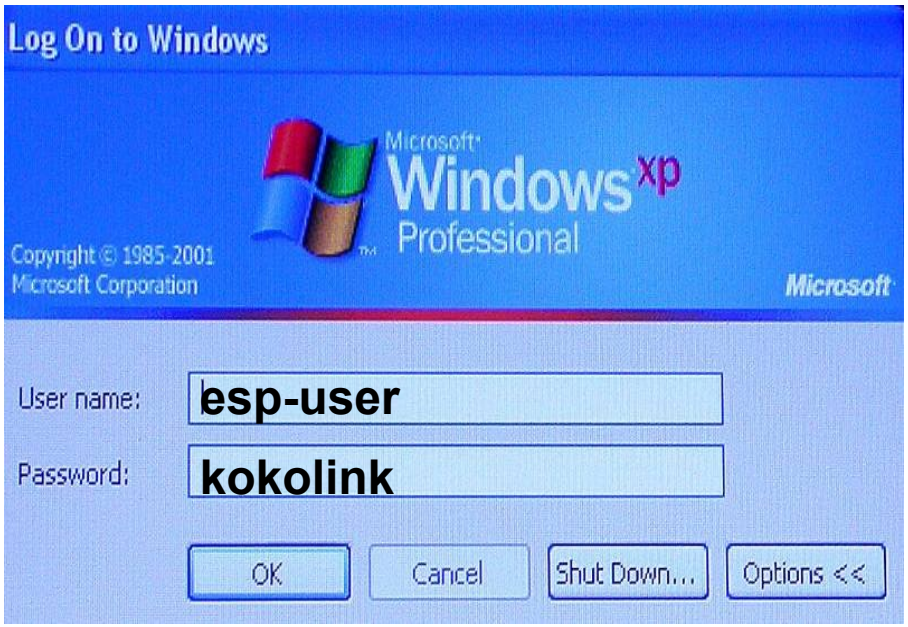

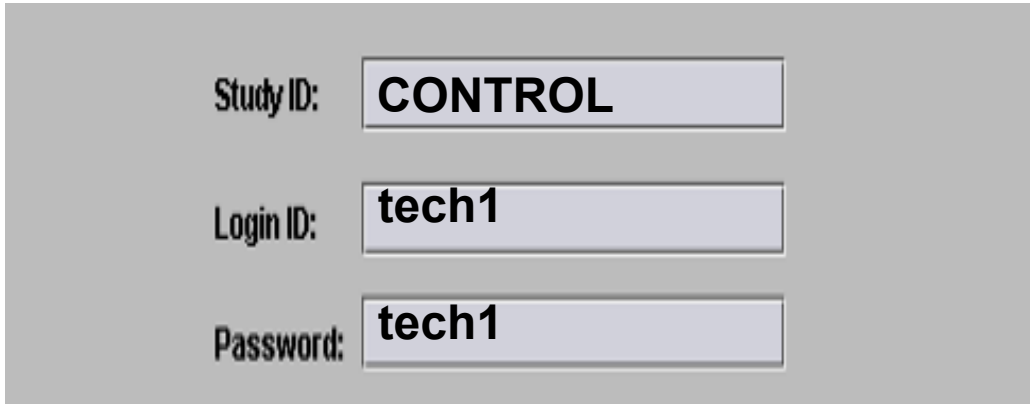

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Subject Testing

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Study Visit Structure

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Visit Name	Interval	Stage	Notes
Visit 1-Screening	Pre FVC	V1 Pre FVC	FEV1 Inclusion
	Post FVC	V1 Post FVC	Reversibility Check
Visit 2-Rand	Pre FVC	V2 Pre FVC	FEV1 Inclusion
	Post FVC	V2 Post FVC	Reversibility Check Stability Check
Visit 3-Week 1	Pre FVC	V3 Pre FVC	Stability Check
	Post FVC	V3 Post FVC	
Visit 4-Week 2	Pre FVC	V4 Pre FVC	Stability Check
	Post FVC	V4 Post FVC	
Visit 5-Week 4	Pre FVC	V5 Pre FVC	Stability Check
	Post FVC	V5 Post FVC	
Visit 6-Week 8	Pre FVC	V6 Pre FVC	Stability Check
	Post FVC	V6 Post FVC	
Visit 7-Week 12	Pre FVC	V7 Pre FVC	Stability Check
	Post FVC	V7 Post FVC	
Visit 8-Week 14	Pre FVC	V8 Pre FVC	Stability Check
	Post FVC	V8 Post FVC	
Early Withdrawal	Pre FVC	EW Pre FVC	
	Post FVC	EW Post FVC	
Unscheduled Visit	Pre FVC	UNS Pre FVC	
	Post FVC	UNS Post FVC	

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Subject Preparation

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Check that patient has:

- Refrained from using SABA within previous 6 hours – NOTE: if subject was not refrained, you will not be able to continue testing. Please contact your monitor regarding rescheduling the visit.
- Has avoided caffeine drinks, alcoholic beverages, large meals and strenuous exercise, per protocol

Clearly explain manoeuvre

Subject should be:

- Seated, upright
- Legs not crossed, feet flat on floor
- Dentures in, if well fitting
- Nose clip on
- Tight seal around mouthpiece

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ATS/ERS Standards: FVC

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- Immediate, maximal exhalation after maximal inspiration. No hesitation.
- No cough in the first second of exhalation.
- Complete exhalation for at least 6 seconds and a good plateau.
- Maximal effort throughout the entire manoeuvre.
- 3 acceptable efforts, with 2 repeatable :

Difference between the largest and second largest FEV1 is ≤150ml.

Difference between the largest and second largest FVC is ≤150ml.

Difference between the largest and second largest PEF is ≤0.67 L/S.

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Spirometry Graphs

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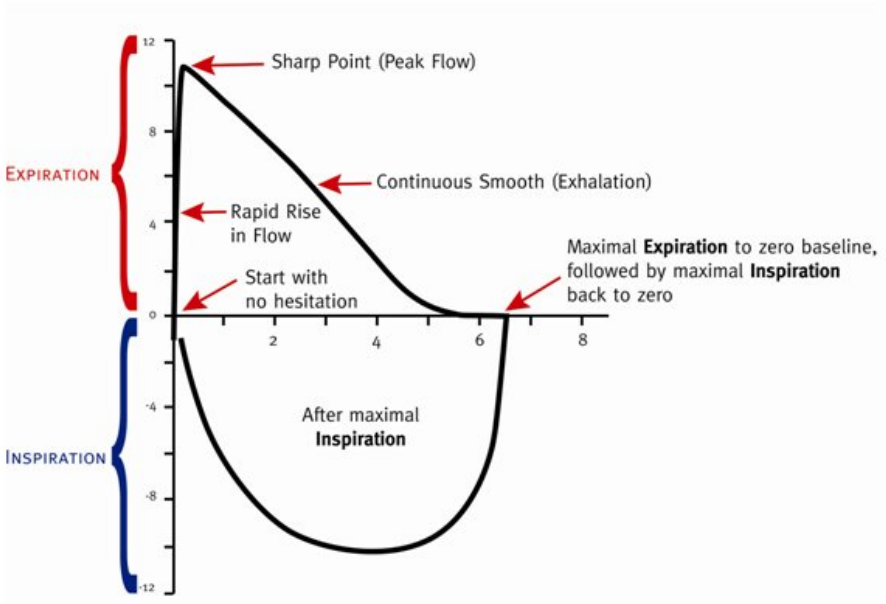
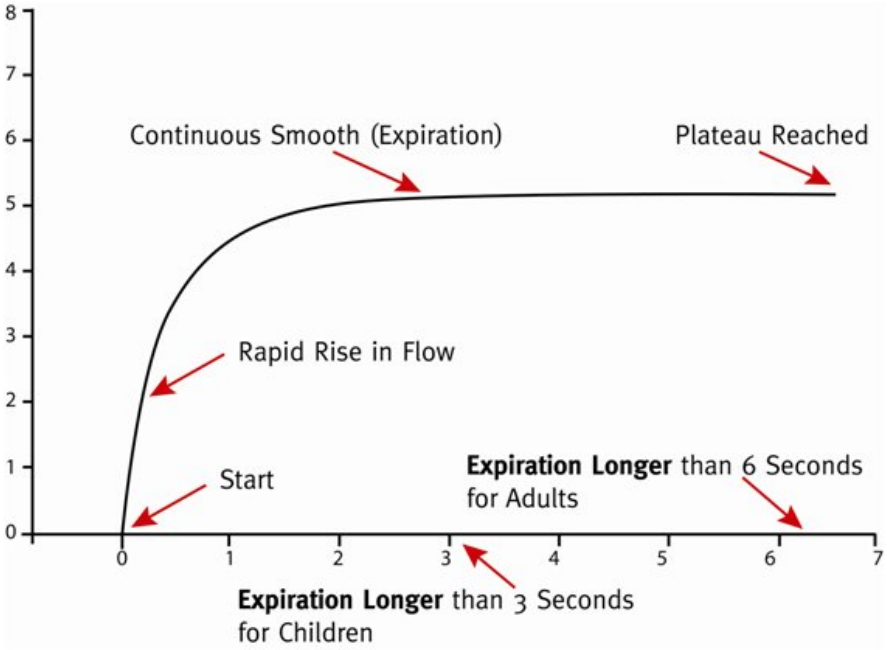
Flow Volume Loop



Volume Time Curve



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FVC Testing Screen

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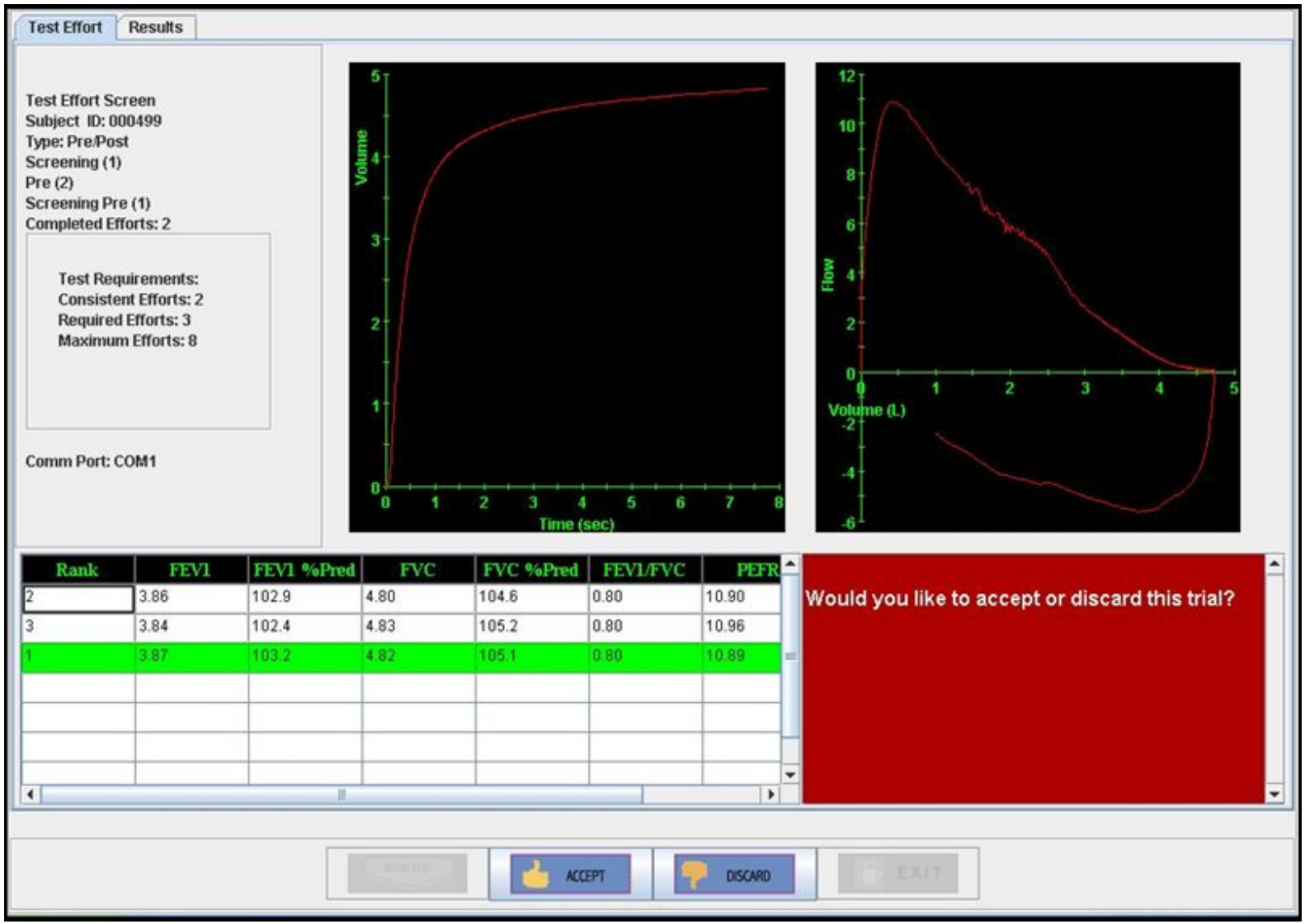

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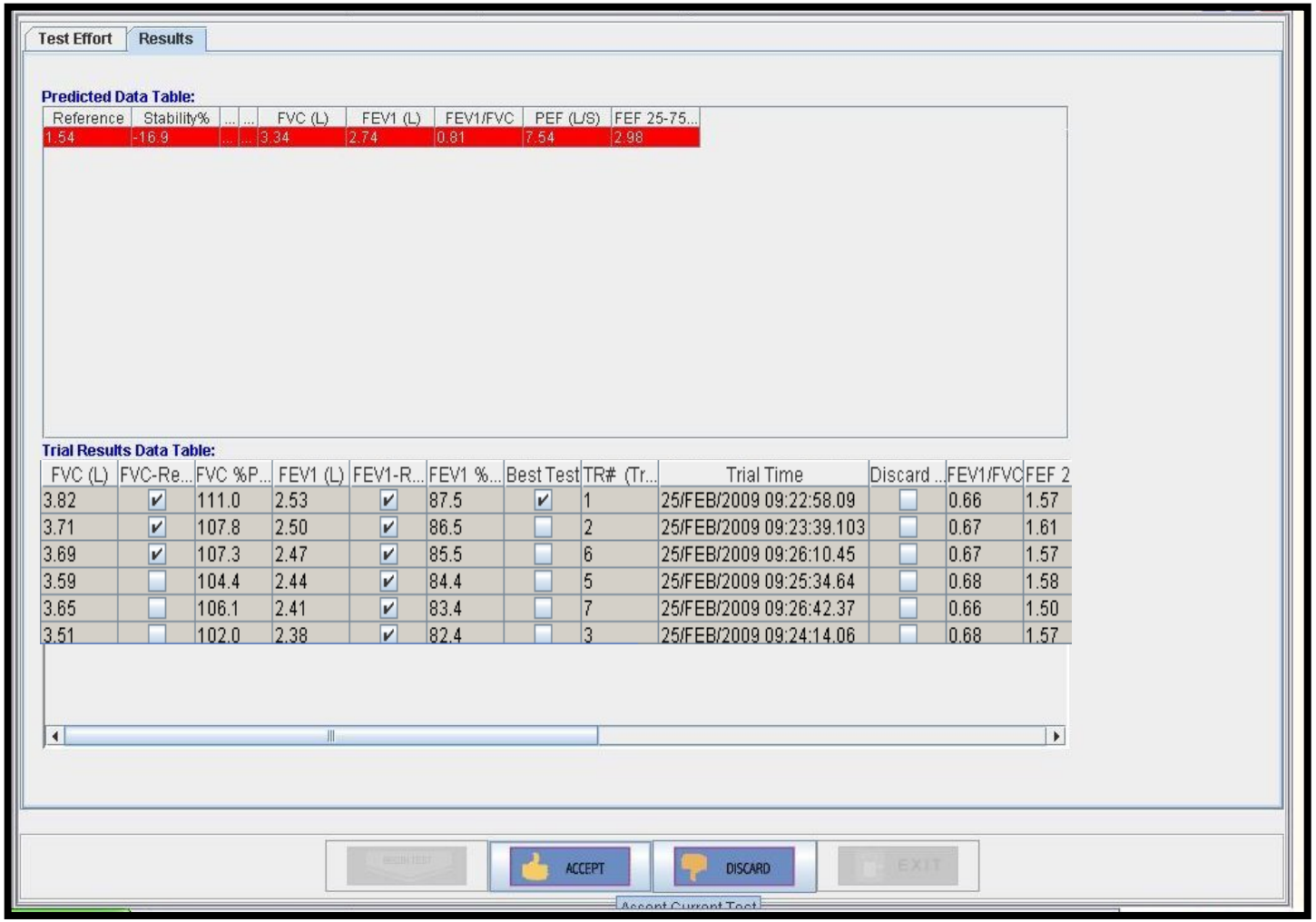
FVC Testing Results Tab

INSPIRING RESPIRATORY HEALTH



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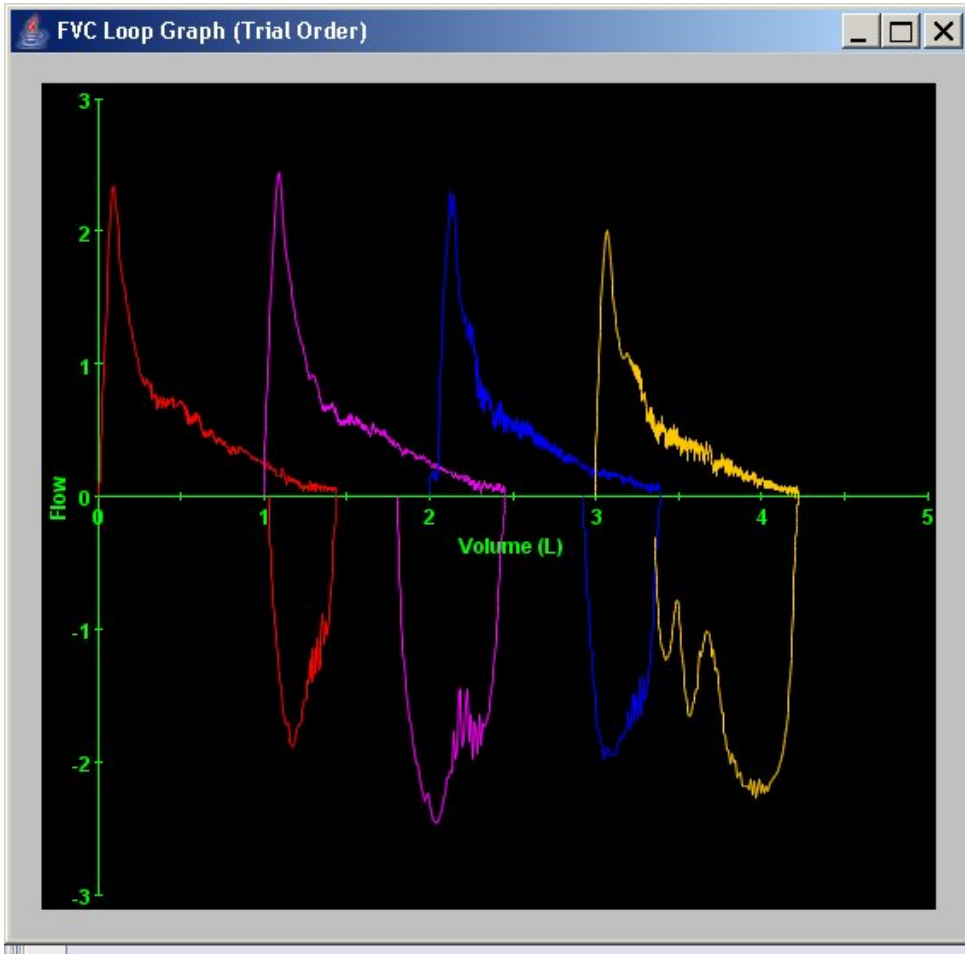
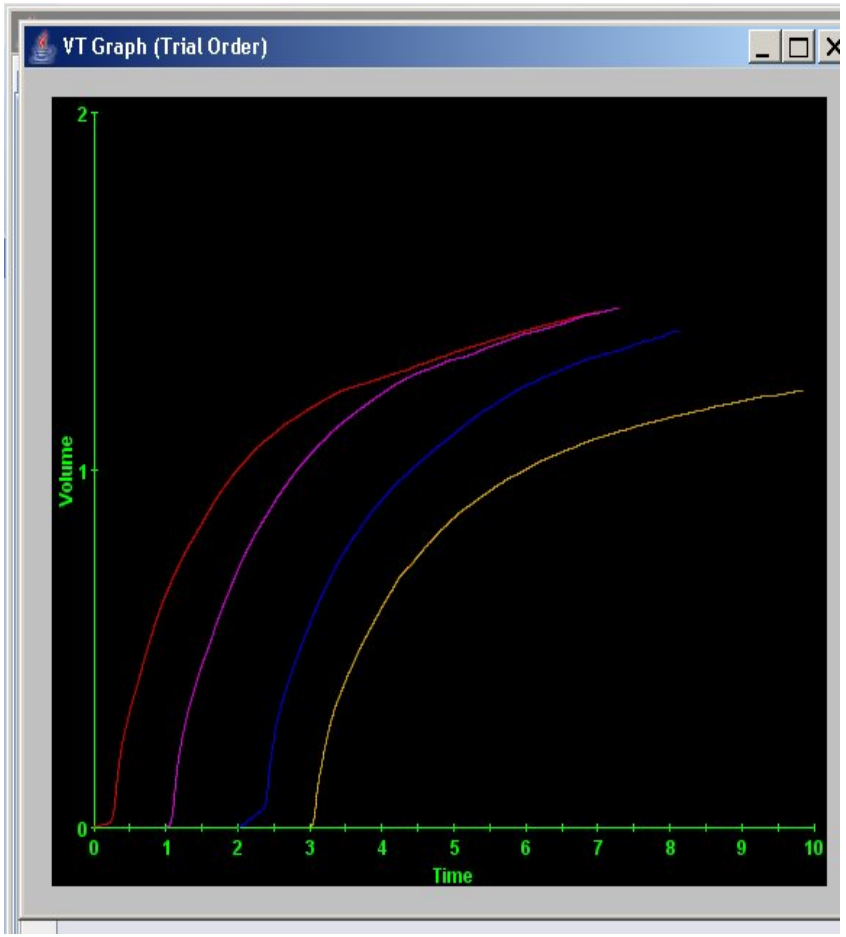
Usable Efforts

INSPIRING RESPIRATORY HEALTH





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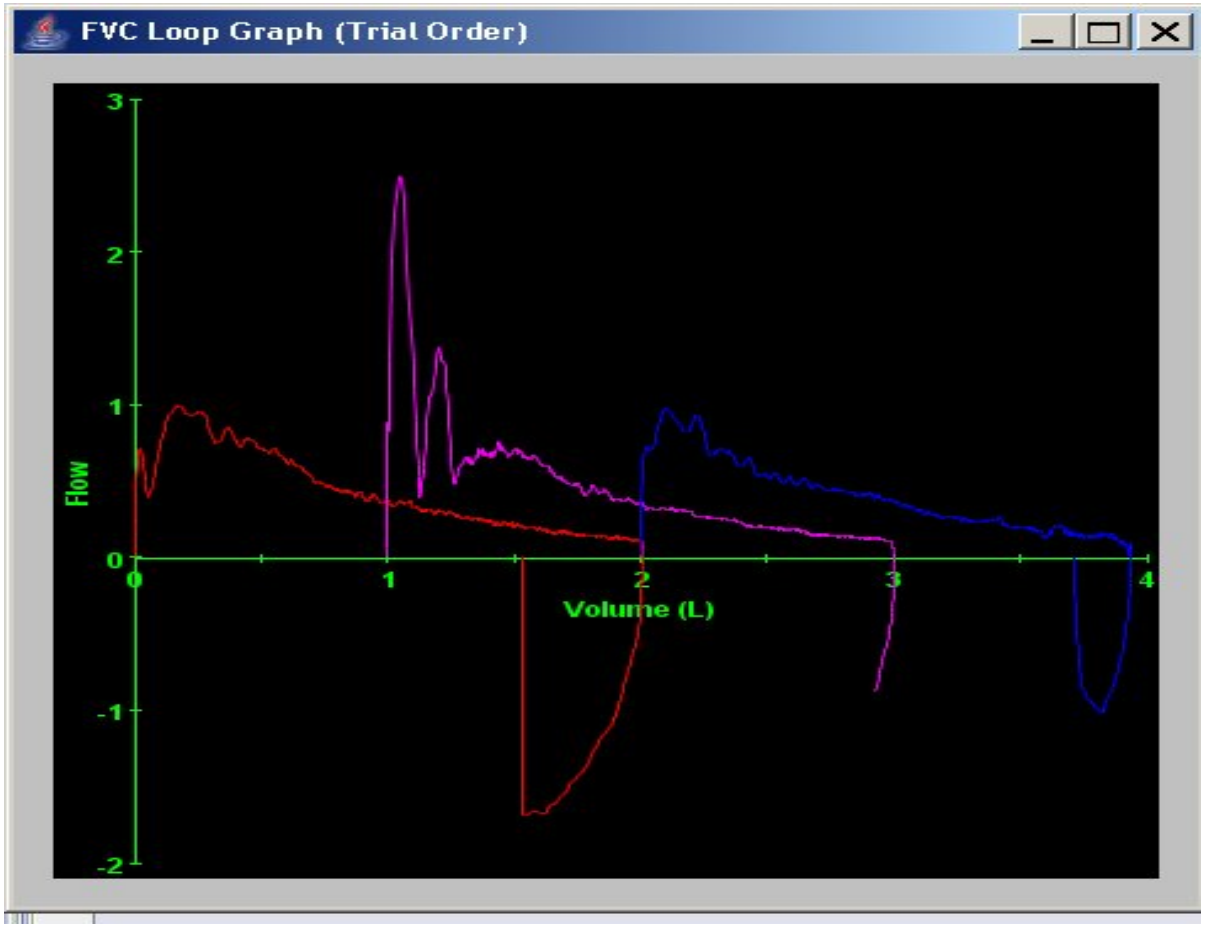
Unacceptable Efforts

INSPIRING RESPIRATORY HEALTH



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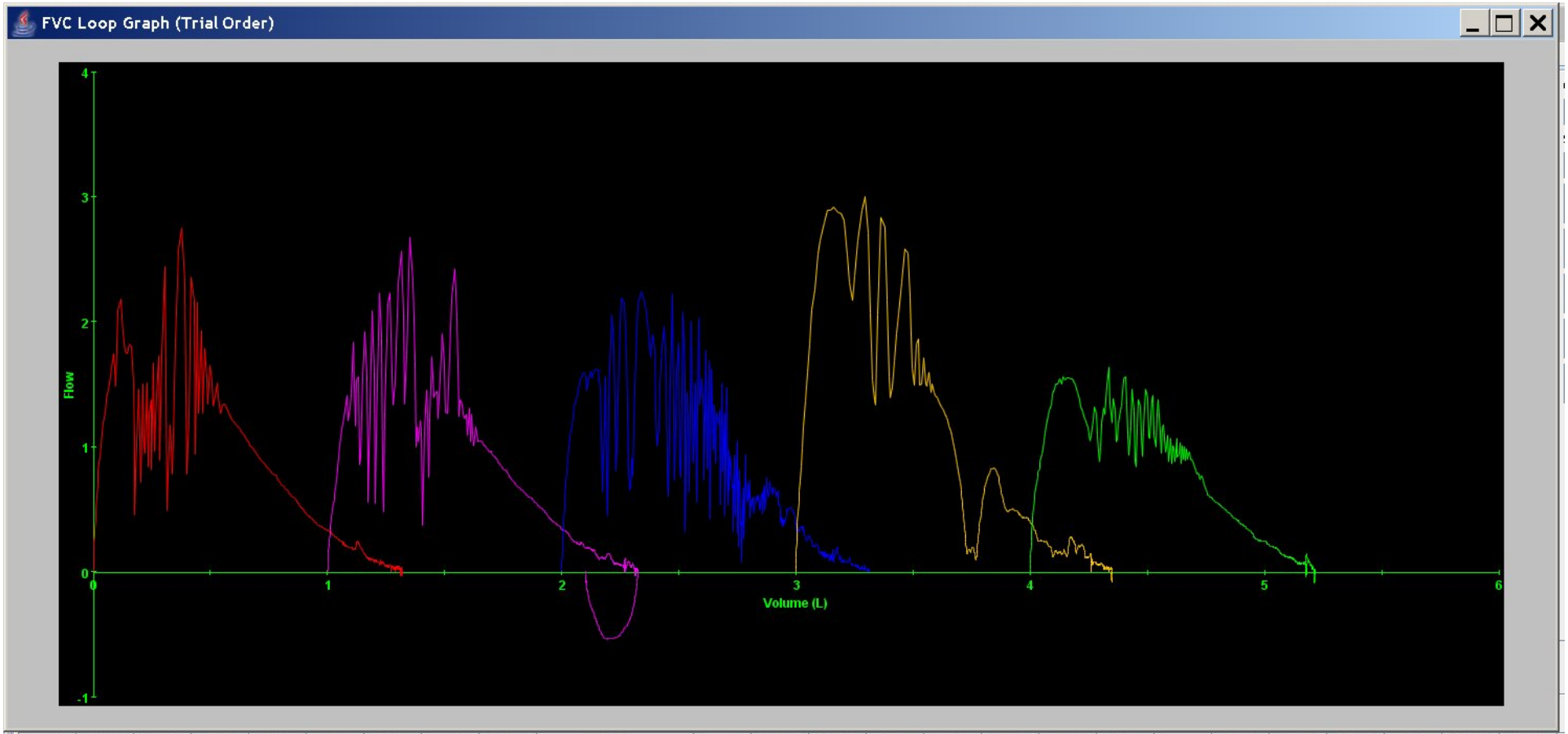
Unacceptable Efforts

INSPIRING RESPIRATORY HEALTH



Graph E...	FVC (L)	FVC-Re...	FVC %P...	FEV1 (L)	FEV1-R...	FEV1 %...	Best Test	TR# (Tr...	Trial Time	Discard ...	FEV1/FVC	FEF 25-...	PEF (L/M)	Exp Tim...	PEFT (...	VEXT %	Flags	Comme...	Rank	PEF %P...	FEV.5 (L)	FEV.5/F...	FEV3 (L)	FEV3/FVC
☑	1.318	☑	112.9	1.005	☑	95.3	☑	5	26/SEP/2008 14:52:54.09	☐	0.77	0.834	164.694	5.790	185.000	10.39	CG PEFT	Tester ...	1	0	0.759	0.58	1.257	0.95
☑	1.326	☑	113.6	1.005	☑	95.3	☐	4	26/SEP/2008 14:51:32.45	☐	0.76	0.839	160.590	6.535	185.000	5.94	CG PEFT	Tester ...	2	0	0.734	0.55	1.261	0.95
☑	1.314	☑	112.6	1.001	☑	94.9	☐	3	26/SEP/2008 14:50:06.17	☐	0.76	0.826	134.406	5.890	170.000	8.47	CG PEFT	Tester ...	3	0	0.740	0.56	1.255	0.96
☑	1.350	☐	115.7	0.918	☐	87.0	☐	2	26/SEP/2008 14:49:03.56	☑	0.68	0.628	180.150	5.510	115.000	1.81		Discard...	101	0	0.736	0.55	1.262	0.93
☑	1.216	☐	104.2	0.918	☐	87.0	☐	1	26/SEP/2008 14:47:35.573	☑	0.75	0.800	97.806	4.930	245.000	2.38	PEFT	Discard...	102	0	0.628	0.52	1.181	0.97

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Quality Flags

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BST - Best Effort

CON - Effort Consistent With Best

AE- Abrupt End to Effort

CG – Cough

6 SEC - Expiration Time < 6 seconds

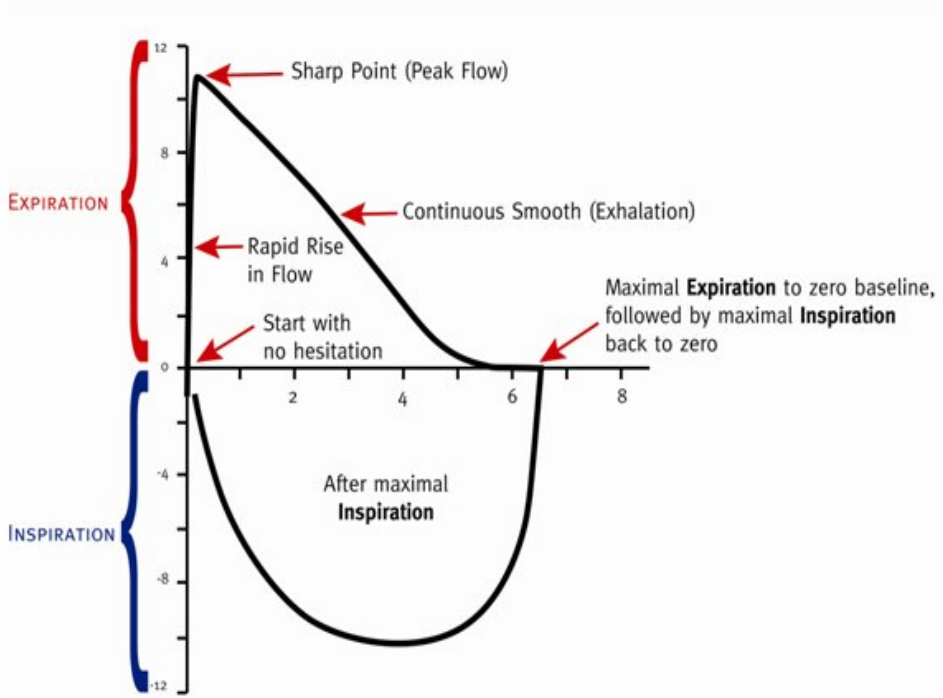
DIS – Discarded Effort

PEFT - PEFT ≥ 150 ms

BE – Back Extrapolation (VEXT)

≥ 5% or 150ml

RB – Rebreathing



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FVC Testing Messages

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- **All FVC stages:** Repeatability status
- **Visits 1 & 2 Pre FVC:** FEV1 Inclusion status
  - FEV1 must be <= 85% of Predicted at both
- **Visit 1 OR V2 Post FVC:** Reversibility Inclusion status
  - Post FEV1 increase must be >= 12% AND >= 200 ml
- **Visits 2 – 8 Pre FVC:** FEV1 and PEF Stability check
  - Warning message will appear if PEF decreases > 30% and/or FEV1 decreases > 20% from Visit 1 baseline

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Demonstration and Practice

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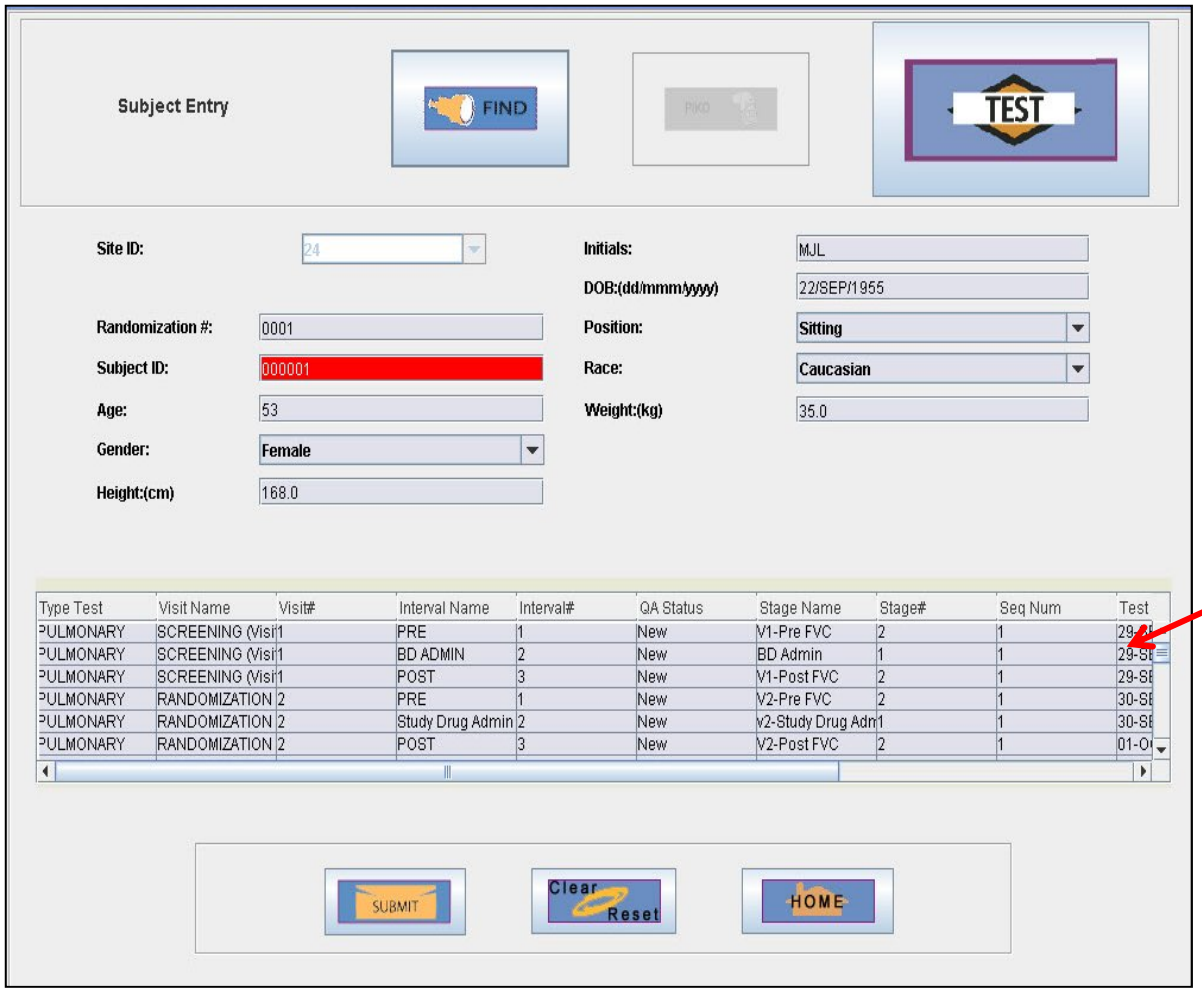
Printing a Report

INSPIRING RESPIRATORY HEALTH



- Subject Entry Screen
- List of tests that have been performed
- Click on the row of the desired test set to print
- System will advance to the Quality Assurance screen

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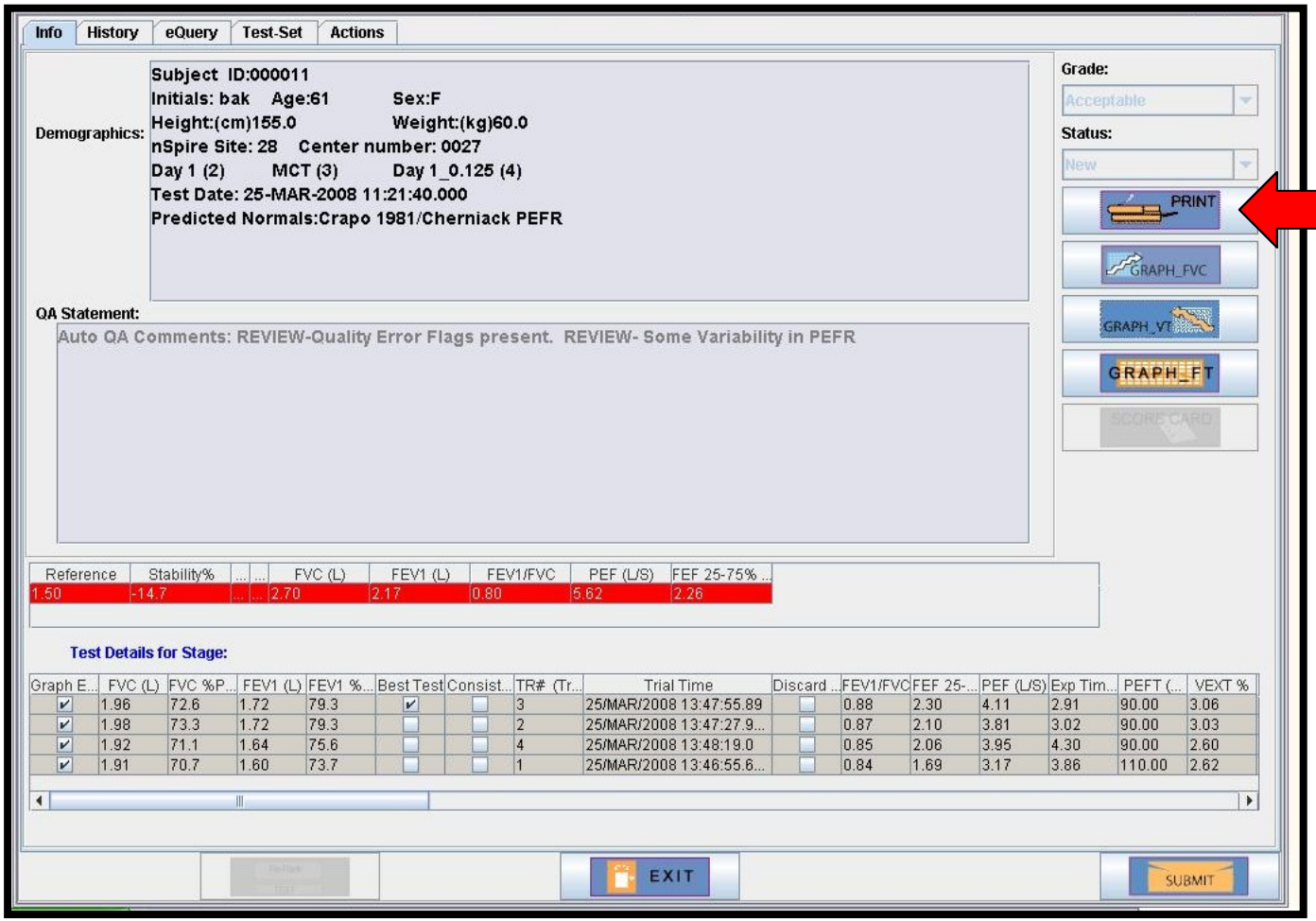
Printing a Report

INSPIRING RESPIRATORY HEALTH



Click on the PRINT button

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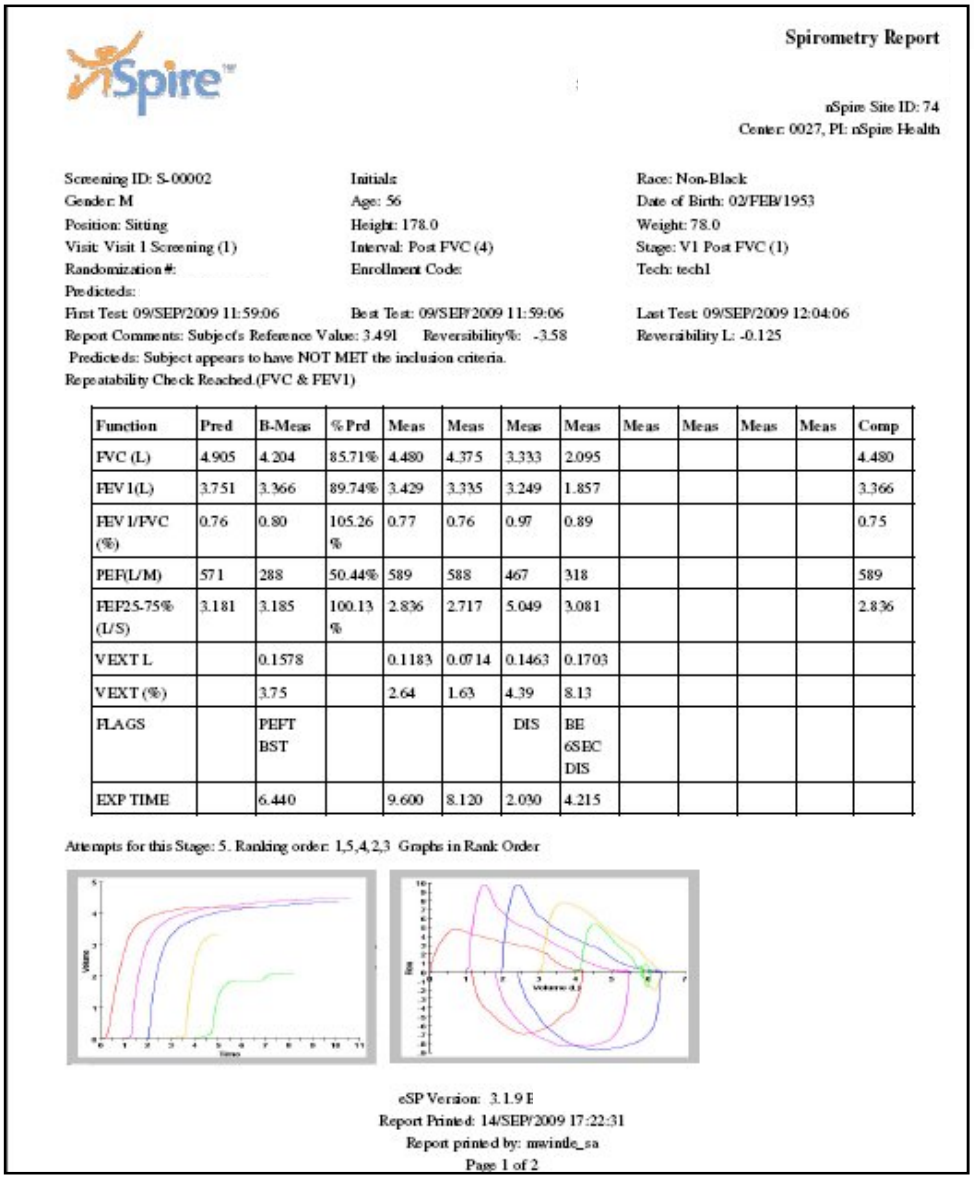
FVC Report

INSPIRING RESPIRATORY HEALTH



Spirometry Report

nSpire Site ID: 74
Center: 0027, PI: nSpire Health

Screening ID: S-00002 | Initials: | Race: Non-Black
Gender: M | Age: 56 | Date of Birth: 02/FEB/1953
Position: Sitting | Height: 178.0 | Weight: 78.0
Visit: Visit 1 Screening (1) | Interval: Post FVC (4) | Stage: V1 Post FVC (1)
Randomization #: | Enrollment Code: | Tech: tech1
Predicteds:
First Test: 09/SEP/2009 11:59:06 | Best Test: 09/SEP/2009 11:59:06 | Last Test: 09/SEP/2009 12:04:06
Report Comments: Subject's Reference Value: 3.491 Reversibility%: -3.58 | Reversibility L: -0.125
Predicteds: Subject appears to have NOT MET the inclusion criteria.
Repeatability Check Reached.(FVC & FEV1)

Function	Pred	B-Meas	% Prd	Meas	Meas	Meas	Meas	Meas	Meas	Meas	Meas	Comp
FVC (L)	4.905	4.204	85.71%	4.480	4.375	3.333	2.095					4.480
FEV1(L)	3.751	3.366	89.74%	3.429	3.335	3.249	1.857					3.366
FEV1/FVC (%)	0.76	0.80	105.26 %	0.77	0.76	0.97	0.89					0.75
PEF(L/M)	571	288	50.44%	589	588	467	318					589
FEF25-75% (L/S)	3.181	3.185	100.13 %	2.836	2.717	5.049	3.081					2.836
VEXT L		0.1578		0.1183	0.0714	0.1463	0.1703					
VEXT (%)		3.75		2.64	1.63	4.39	8.13					
FLAGS		PEFT BST				DIS	BE 6SEC DIS					
EXP TIME		6.440		9.600	8.120	2.030	4.215					

Attempts for this Stage: 5. Ranking order: 1,5,4,2,3 Graphs in Rank Order

eSP Version: 3.1.9 E
Report Printed: 14/SEP/2009 17:22:31
Report printed by: mwintle_sa
Page 1 of 2

Study Name
nSpire site ID Number
Center number
PI name

Demographics of the patient

Report Comments which can include information about inclusion, repeatability and stability

Function = Reported Values
Pred = Predicteds
B-Meas = Best Test
% Prd = Percentage of predicted
Meas = Other efforts performed
Comp = Best Values (Composite)

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FVC Testing Summary

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- What are the requirements for acceptable testing?
- What does PEFT flag signify?
- What do you do if 1 of 3 efforts performed has a ‘flag’?
- At which visits do you check inclusion status?
- How often do you perform calibration?

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Study Specific Communication Process: eQueries

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eQueries or Electronic DCCFs

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As a part of nSpire's Centralized Quality Control services, each test and effort is individually reviewed to determine the quality of the data and acceptability according to the ATS/ERS 2005 and protocol guidelines.

- eQuery is a feature within the system software that allows communication between the site and nSpire Health.
- eQueries are created for test sets, i.e. Pre FVC, Post FVC
- The eQueries will be uploaded to the site during the routine synchronizations.

The site must respond to EVERY eQuery until resolution.

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eQueries or Electronic DCCFs

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Items communicated via eQueries are:

- adjustments to spirometry test results
- demographic data discrepancies
- protocol non-compliance
- missing or incomplete visits

eQueries will be generated, at minimum, for:

- unacceptable test sets
- selection of new best effort
- discarded efforts considered acceptable

eQuery Resolution

Sites must respond to every eQuery until resolution.

If this doesn't occur in a timely manner, nSpire Heath will escalate to Actelion.

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eQuery Notification

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The mailbox indicates there are new eQueries pending your review and response. Click on the red *Mailbox* to open a list of test sets with new eQueries.

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eQuery *To Do* List

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TO DO LIST Display Selection = PFT In Progress Number of Records=579

	Status	Grade	Site	Screening ID:	Visit Name	Visit #	Interval Name	Interval #	Stage Name	Stage #	Visit Date	Test Seq#	Trial Date	State
Row 1	In Progress	Other	271	S-00006	Visit 2 Baseline	2	Pleth Entry	5	V2 Pleth Entry	1	20/SEP/2010 08:2	1	20/SEP/2010 09:4	QUE-
Row 2	In Progress	Acceptable	271	S-00001	Visit 5	5	Pre FVC	2	V5 Pre FVC	1	16/SEP/2010 09:0	1	16/SEP/2010 09:1	Accep
Row 3	In Progress	Borderline Accept	271	S-00006	Visit 1 Screening	1	Post FVC	4	V1 Post FVC	1	14/SEP/2010 08:4	1	14/SEP/2010 09:3	Subje
Row 4	In Progress	Acceptable	271	S-00006	Visit 1 Screening	1	Pre FVC	2	V1 Pre FVC	1	14/SEP/2010 08:4	1	14/SEP/2010 08:4	NOTE
Row 5	In Progress	Borderline Accept	271	S-00005	Visit 5	5	Post FVC	4	V5 Post FVC	1	09/SEP/2010 08:3	1	09/SEP/2010 09:3	Incon
Row 6	In Progress	Borderline Accept	271	S-00005	Visit 4	4	Pre FVC	2	V4 Pre FVC	1	02/SEP/2010 08:1	1	02/SEP/2010 08:2	Recal
Row 7	In Progress	Borderline Accept	271	S-00004	Visit 4	4	Post FVC	4	V4 Post FVC	1	01/SEP/2010 09:0	1	01/SEP/2010 09:5	Borde
Row 8	In Progress	Acceptable	271	S-00002	Visit 2 Baseline	2	Pleth Entry	5	V2 Pleth Entry	1	26/AUG/2010 08:1	1	26/AUG/2010 09:4	QUE-
Row 9	In Progress	Borderline Accept	271	S-00005	Visit 2 Baseline	2	Pleth Entry	5	V2 Pleth Entry	1	26/AUG/2010 07:2	1	26/AUG/2010 17:4	QUE-
Row 10	In Progress	Borderline Accept	271	S-00004	Visit 2 Baseline	2	Pleth Entry	5	V2 Pleth Entry	1	25/AUG/2010 08:0	1	25/AUG/2010 10:2	QUE-
Row 11	In Progress	Borderline Accept	271	S-00002	Visit 1 Screening	1	Pre FVC	2	V1 Pre FVC	1	20/AUG/2010 08:1	1	20/AUG/2010 08:2	Borde
Row 12	In Progress	Borderline Accept	271	S-00005	Visit 1 Screening	1	Pre FVC	2	V1 Pre FVC	1	20/AUG/2010 07:2	1	20/AUG/2010 07:3	Borde
Row 13	In Progress	Borderline Accept	271	S-00001	Visit 1 Screening	1	Pre FVC	2	V1 Pre FVC	1	18/AUG/2010 09:3	1	18/AUG/2010 09:3	NOTE
Row 14	In Progress	Borderline Accept	271	S-00003	Visit 1 Screening	1	Pre IC	1	V1 Pre IC	1	18/AUG/2010 08:4	1	18/AUG/2010 08:4	QUE-
Row 15	In Progress	Borderline Accept	271	S-00003	Visit 1 Screening	1	Pre FVC	2	V1 Pre FVC	1	18/AUG/2010 08:4	1	18/AUG/2010 08:5	Borde
Row 16	In Progress	Borderline Accept	271	S-00004	Visit 1 Screening	1	Pre FVC	2	V1 Pre FVC	1	18/AUG/2010 08:0	1	18/AUG/2010 08:1	Borde

From the To Do list, click on the test file you want to review. Each row represents an individual eQuery file that must be answered.

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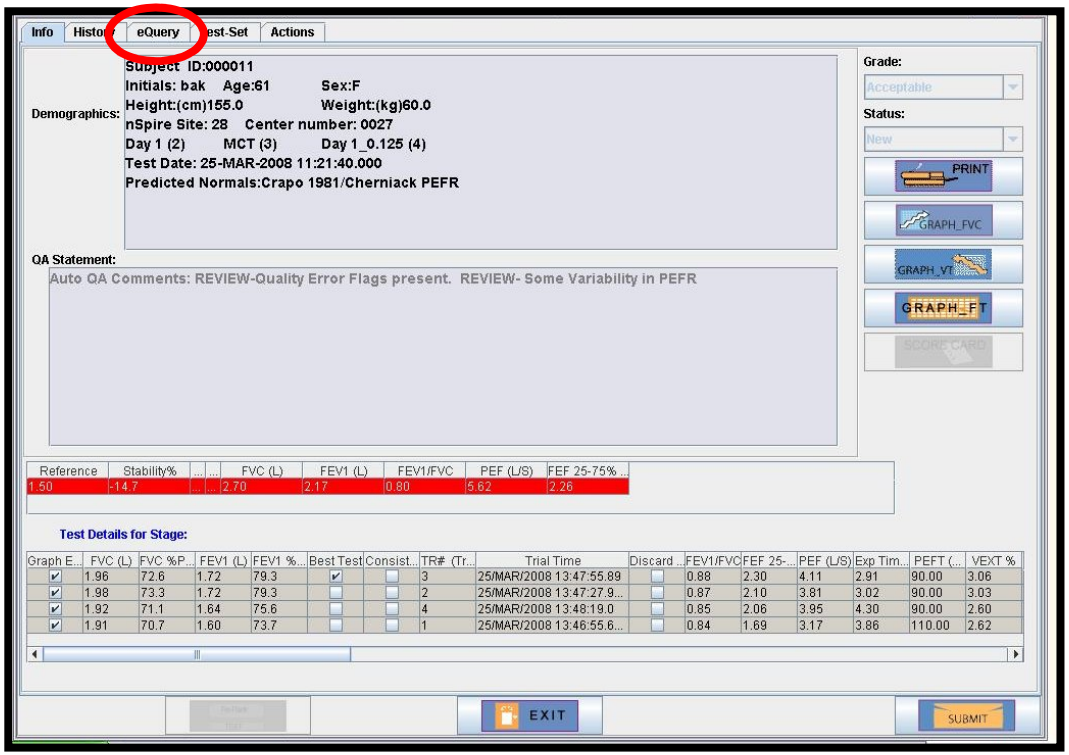
Responding to eQueries

INSPIRING RESPIRATORY HEALTH



After selecting the eQuery file the software will advance to the QA review screen for that file, as shown on the left.

Click on the **eQuery Tab** to review the equery.

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Responding to eQueries

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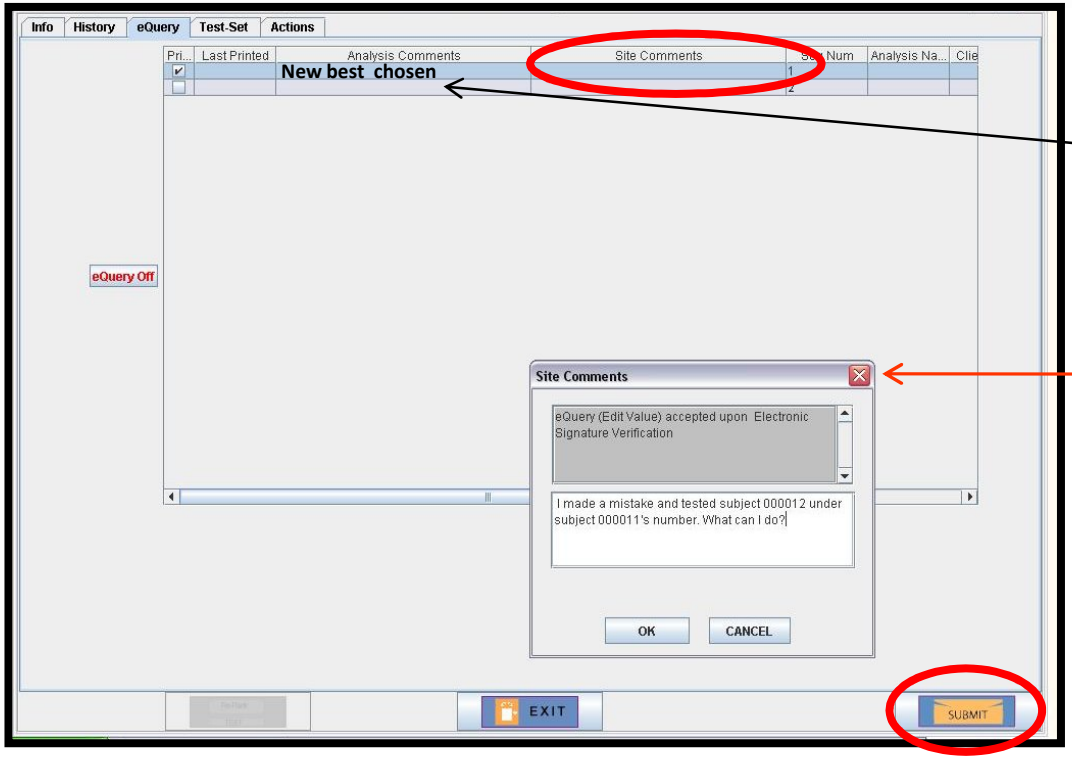

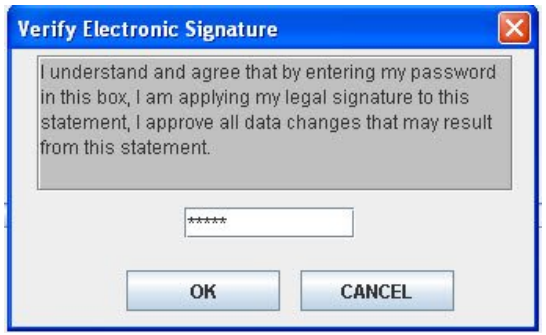

- To view the eQuery, click on the text in the Analysis Comments field.
- To respond, click into the *Site Comments* field directly to the right of the Analysis Comments.
- The *Site Comments* dialog box appears. Type in your comments and click OK.
- When prompted, enter your password (electronic signature).

- Click on the **Submit** button to **save** your comments.

If you do not press Submit the eQuery will not be saved or transmitted.

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Creating an eQuery

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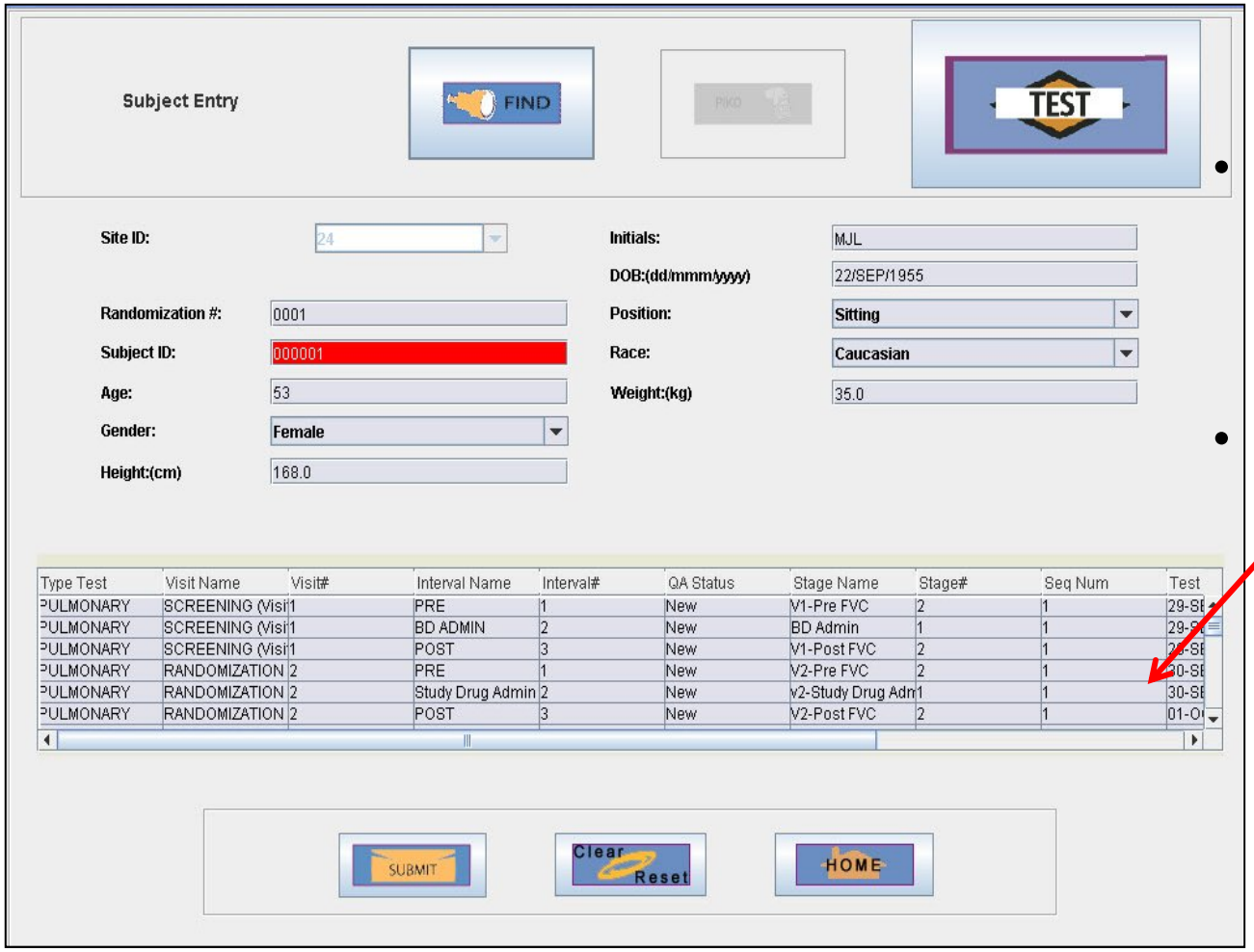

- eQueries are created for test sets
- On the **"Subject Entry"** Screen, select the test set you want to use

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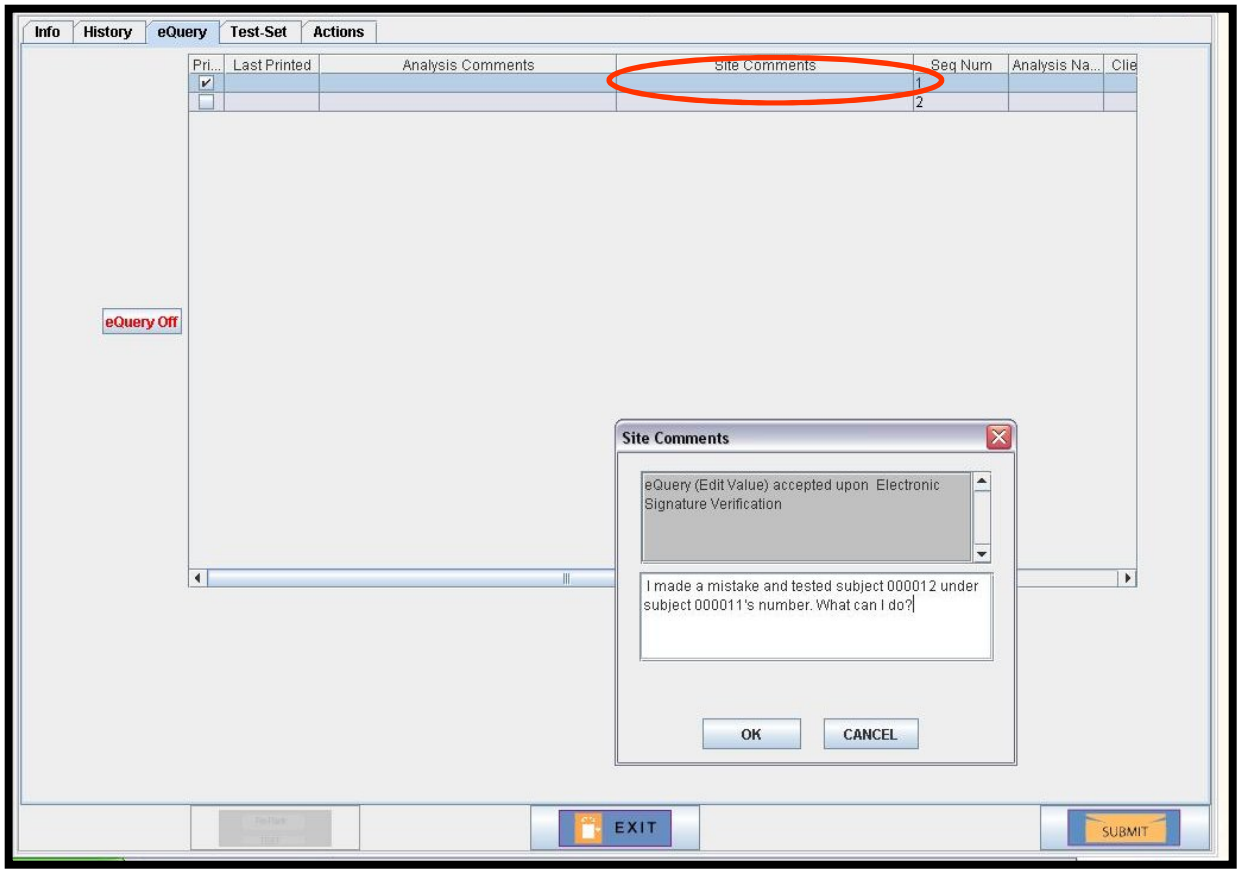
Creating an eQuery

INSPIRING RESPIRATORY HEALTH



1. Put the cursor in the Site Comments Field
2. The Site Comments Box will come up. Type in your comments, question, concern, etc.
3. Click **"OK"**
4. Verify your electronic signature
5. Click on the **"Submit"** Button

NOTE: If you forget to click on the "Submit" Button the query will not be saved or transmitted

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eQuery Summary

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- **Red Mailbox on Home Screen indicates _____?**
- **What type of issues are communicated?**
- **How often should you check for eQueries?**
- **What must you do to save your equery response and send it to nSpire?**

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Exiting eSP

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- Click on "**Exit**" when "logging off" but not closing the eSP application
- Click on the "**X**" box in the upper right hand corner of the window when you are closing out of the eSP application

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Customer Support

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We provide 24 hour technical support via our Help Desk with toll free number provided for your country

Contact us with:

- Equipment Issues
- Software Questions or Issues
- Spirometry Related Protocol Questions
- Problems with Synchronization
- Supply orders

Please **leave a message** if an agent does not pickup immediately. Include your name, site number, study, contact information and brief explanation of the issue.

An e-mail alert containing your message will be sent to all Helpdesk agents letting them know a call was received. Your call will be returned, if requested.

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FAQs

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1. How are demographic changes made?

   Make all demographic changes on the subject screen. You will be required to note a reason for the change.

2. What if the site administrator leaves?

   Ask them to create an account for the new administrator before they leave, OR

   Contact nSpire technical support to reset the PI Admin account (First six letters of PI's last name.)

3. What if a new technician is hired?

   Follow the certification process in users guide.

4. After Synchronization, must the system stay connected during testing?

   No, the system can be disconnected during testing.

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5. Must calibrations be done every day?

   Yes, as in this study you cannot predict when a subject will be available for testing and calibration must be performed prior to testing.

6. Can the laptop be left on overnight?

   No. Please shutdown at the end of the day.

7. How are passwords reset?

   Your site administrator can reset your password. nSpire's Help Desk can also reset the password.

8. Can I move the laptop without shutting it off?

   Yes, if you don't close the lid. Closing the lid, or leaving it idle for a long time, puts it into hibernation mode, and you will lose the connection to the Koko handle.

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Questions?

Technician enablement process follows

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